510(k) SUMMARY

SPONSOR NAME: Amedica Corp.
615 Arapeen Drive
Suite 302
Salt Lake City, Utah 84108

510(k) CONTACT: Robert M. Wolfarth
Phone: (801) 583-5100
E-Mail: Robert@AmedicaCorp.com

TRADE NAME: Vented Cement Restrictor

COMMON NAME: Instrument, Surgical, Sonic and Accessory/Attachment

CLASSIFICATION: Instrument, Surgical, Sonic and Accessory/Attachment (Product Code 87 JDX) are Class II per 21 CFR §888.4580, reviewed by the Orthopedic Devices panel.

PREDICATE DEVICES:

- Amedica Vented Cement Restrictor (K022729)
- Quantum Orthopedics Cement Restrictor (K040276)

DEVICE DESCRIPTION:
The Vented Cement Restrictor used in cemented applications for hip, knee, and shoulder arthroplasty, is a polymeric device. The Vented Cement Restrictor features a ball valve which safely vents air trapped distally to the stem, thus alleviating distal intra-medullary air pressure related embolisms. This ball may be manufactured from either the above material or from a ceramic material.

INTENDED USE:
The Vented Cement Restrictor is intended for use as a cement restrictor used in the treatment of the following:

- Total Hip Arthroplasty
- Total Knee Arthroplasty
- Total or Hemi Shoulder Arthroplasty

The device is not intended for use in spinal surgeries.

BASIS OF SUBSTANTIAL EQUIVALENCE:
Performance tests, design comparisons, and functional analyses conducted on the Vented Cement Restrictor demonstrate that it is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 15 2005

Mr. Robert M. Wolfarth
Director of Quality Assurance and Regulatory Affairs
Amedica Corporation
615 Arapeen Drive, Suite 302
Salt Lake City, Utah 84108

Re: K050699
Trade/Device Name: Vented Cement Restrictor
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: JDK
Dated: March 17, 2005
Received: March 18, 2005

Dear Mr. Wolfarth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050699

Device Name: Vented Cement Restrictor

Indications for Use:

The Vented Cement Restrictor is intended for use as a cement restrictor used in the treatment of the following:

- Total Hip Arthroplasty
- Total Knee Arthroplasty
- Total or Hemi Shoulder Arthroplasty

The device is not intended for use in spinal surgeries.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K050699

(Posted November 13, 2003)